Department of Defense
DIRECTIVE

December 6, 1985
NUMBER 6000.8

ASD(HA)

SUBJECT: Funding and Administration of Clinical Investigation Programs

References: (a) DoD Directive 6000.4, "Clinical Investigation Program," April 16, 1976 (hereby canceled)
(b) DoD Directive 6015.3, "Provision of Beds for Participants in Clinical Research Programs", January 19, 1968. (hereby canceled)
(c) DoD Instruction 7230.7, "User Charges," January 29, 1985
(d) Title 10, United States Code, Sections 5178 and 2113
(e) through (n), see enclosure 1

A. REISSUANCE AND PURPOSE

This Directive reissues reference (a), supersedes reference (b) to update DoD policy, procedures, and responsibilities regarding:

1. Clinical Investigation Programs (CIPs) in military Medical Treatment Facilities (MTF), Dental Treatment Facilities (DTF), and in the Uniformed Services University of the Health Sciences (USUHS).

2. The administration and funding of CIPs within the Department of Defense.

B. APPLICABILITY AND SCOPE

1. This Directive applies to the Office of the Secretary of Defense (OSD), the Military Departments, and the USUHS.

2. This Directive encompasses all elements of a CIP relating to the medical mission of the Military Departments and the USUHS, except those projects sponsored by the Under Secretary of Defense Research and Engineering (USD(RE)), and basic biomedical science research and clinical investigation projects at USUHS.

C. DEFINITIONS

The terms used is this Directive are defined in enclosure 2.

D. POLICY

It is DoD policy that:

1. Clinical investigation is an essential component of medical care and teaching that is intended to achieve the following objectives:

a. Improve the quality of patient care.

b. Generate an atmosphere of inquiry responsive to the dynamic nature of the health sciences.

c. Promote high professional standing and accreditation of health education programs.

2. CIPs shall be funded from operating funds from Major Defense Program 8 and with procurement funds. Supplementation of these funds with grants or gifts shall be in accordance with this Directive. Any reimbursement for costs in conjunction with a CIP shall be in accordance with DoDI 7230.7, (reference (c)).

3. The Board of Regents of USUHS, in accordance with 10 U.S.C. 2113 (reference (d)), is authorized to accept, hold, administer, invest, or spend any gift made to the University, and to enter into contracts with the Henry M. Jackson Foundation for the Advancement of Military Medicine, or with any other nonprofit entity for the purpose of carrying out medical research, medical consultation, and medical education at USUHS or an affiliated MTF or DTF.

4. DoD health care personnel are prohibited from accepting any compensation in addition to their salaries for performing duties within the scope of a CIP.

5. Military contingency requirements take precedence over the requirements of the CIP.

6. In conducting clinical investigations, there may be no competition with available commercial facilities in providing services to entities outside the Federal Government.

E. PROCEDURES

1. The initiation of a grant request by the principal investigator to support a clinical investigation study is the means for obtaining Program 8 funding. Administrative costs and permanent staff of the CIP may be supported by existing official funding mechanisms. Grants from federal sources outside of the Department of Defense are received under procedures prescribed by 10 U.S.C. 2601 (reference (e)), 42 U.S.C. 225a (reference (f)), 10 U.S.C. 2113 reference (d), or DoD 4000.19-R (reference (g)), as applicable.

2. Gifts may be used to provide funds for a clinical investigation study. Funds other than those cited in subsection E.1., above, shall be considered gifts, and shall be received under procedures prescribed by 10 U.S.C. 2601 (reference (e)), which governs gifts to the Government; 50 U.S.C. 1151 (reference (h)), which governs gifts for defense purposes; or by reference (d), as applicable.

3. The donation of a gift for a clinical investigation study shall be accounted for in accordance with the following guidelines to prevent conflict of interest or the appearance of impropriety:

a. Drugs, placebos, biologics, and medical devices not commercially available, shall be excluded from the requirements of this Directive. These items shall be accepted in writing in accordance with the Military Service's regulations or 10 U.S.C. 2113 (reference (d)), as applicable. Items shall not be used until the protocol for the clinical investigation study has been approved. All drugs shall be received, stored, and controlled by the pharmacy, and none shall be dispensed without an approved protocol.

b. Requests for gifts shall not be initiated by DoD health care providers. Completion of standard applications for nonfederal research funds is allowed in accordance with the requirements of this Directive governing grants.

c. The donor shall be notified in writing that the gift shall be made to the Government on behalf of the MTF, DTF, or USUHS, as applicable, and is not for the personal use of an individual.

d. When a gift is being considered for receipt, the following written information shall be provided to the MTF/DTF Commander or the President of USUHS prior to receipt of any gift:

(1) For personal property; a description of item(s), cost of the item(s), quantity provided, projected use, any expense anticipated in receiving or utilizing the item, and the ultimate disposition of the item(s) on loan, which shall be returned upon completion of the study as is, where is.

(2) For a gift of funds; a description of how the money shall be used in support of the CIP and a statement of the donor's current or prospective business relationship with the Department of Defense shall be provided.

e. The MTF/DTF Commander, or the President, USUHS, shall recommend the acceptance or nonacceptance of the gift. The procedures for acceptance of gifts shall be in accordance with the Military Service's implementing regulations governing 10 U.S.C. 2601 (reference (e)) and 2113 (reference (d)), as applicable.

f. It is the prerogative of the Secretary of the Military Department and of the President, USUHS, to refuse any gift.

g. An offer of a nonmonetary gift requiring substantial expenditures of funds or administrative efforts shall be evaluated carefully to determine whether acceptance is desirable.

h. No arrangements shall be made that give special privileges or concessions to the donor.

4. Grants or gifts received for CIPs shall be administered by an officer designated by the MTF/DTF Commander, or President, USUHS. This officer shall be someone other than the principal investigator or anyone directly involved in the conduct of the study. Disbursements to DoD from cooperative grants held by non DoD institutions shall also be administered by a designated officer not directly involved in the conduct of the study.

5. Grants or gifts shall be accounted for, and used in accordance with DoDD 5500.7, (reference (i)), the applicable Military Department regulations, and USUHS regulations that prevent conflict of interest, or the appearance of conflict of interest, for DoD health care personnel.

6. Disbursement of the grant or gift funds shall be subject to Military Service regulations (i.e. the total amount for travel shall not exceed the Government per diem rates) or USUHS instructions, as applicable.

7. Any gift funds to the military services not expended shall be reprogrammed in accordance with Military Department regulations. Any grant funds not expended in the clinical investigation study shall be refunded to the grantor by the designated facility, or reprogrammed at the direction of the grantor.

8. For grants, a document shall be signed by the Commander of the designated facility and a representative of the grantor, specifying the nature of the grant, including monetary value, requests of the grantor, and the conditions under which the designated facility accepts the grant, as well as a statement that the investigation shall be subject to delay or termination if required, in the interest of the military mission.

9. For gifts a document shall be signed by the Commander of the designated facility and forwarded to the donor, specifying the nature of the gift, including monetary value, requests of the donor, and the conditions under which the designated facility accepts the gift, as well as a statement that the conduct of the study shall be subject to delay or termination if required, in the interest of the military mission.

10. When DoD civilian employees volunteer to provide service within the scope of their employment, any duty performed during the employee's regularly scheduled duty day, shall be considered constructive duty for which straight time rates apply. Employees must have the approval of their immediate supervisor to participate during duty time. Participation outside the employee's scheduled duty, or during leave, will be considered voluntary overtime for which payment or compensatory time must be granted, as mandated by the Fair Labor Standards Act. These limitations on the provision of volunteer services by civilian employees shall be documented and signed off by the employee and his or her supervisor prior to participating in the clinical investigation study.

11. Active duty military personnel, retirees, dependents, and others entitled to care in military MTFs and DTFs may participate as human subjects in accordance with the requirements of DoD 3216.2 (reference (j)).

12. Active duty military may participate as human subjects, but may not be compensated for participation except when blood is furnished in accordance with 24 U.S.C. 30 (reference (k)).

13. Retired military personnel, dependents, and others entitled to medical care in military facilities may participate as human subjects. These persons may be compensated on a fee basis prusuant to a contract, in accordance with 5 U.S.C. 5532 (d)(2) reference (l)).

14. It is U.S. policy (31 U.S.C. 1342 (reference (m)) not to accept voluntary services from private citizens when the services may provide a basis for a future claim against the Government for their value. Therefore, such services shall be accompanied by a statement signifying that the individual acknowledges that he or she will not be entitled to any compensation for these services or future claim. Private citizens may enter into an independent contractor relationship, and participate for a fee in accordance with the procedure endorsed by the Comptroller General Opinion 649 (reference (n)).

F. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Health Affairs)(ASD(HA)) shall monitor the implementation of this Directive.

2. The Secretaries of the Military Departments, or their designees, shall establish programs for clinical investigation, and ensure compliance with this Directive.

3. The Surgeon General of each Military Department shall establish policy to ensure compliance with this Directive within the MTFs and DTFs of his or her respective Military Department and report the number, content and funding of CIP grants to ASD(HA) annually.

4. The President of the Uniformed Service University of Health Sciences (USUHS) shall ensure compliance with applicable portions of this Directive for USUHS and report the number, content and funding of CIP grants to ASD(HA) annually.

G. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs)(ASD(HA)) within 120 days.

William H. Taft, IV
Deputy Secretary of Defense

Enclosures - 2
1. References
2. Definitions

References, (Continued)

(e) Title 10, United States Code, Section 2601
(f) Title 42, United States Code, Section 225a
(g) DoD 4000.19-R, "Defense Regional Interservice Support (DRIS) Regulation," March 1984, authorized by DoD Directive 4000.19, October 14, 1980
(h) Title 50, United States Code, Section 1151
(i) DoD Directive 5500.7, "Standards of Conduct," January 15, 1977
(j) DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research," January 7, 1983
(k) Title 24, United States Code, Section 30
(l) Title 5, United States Code, Section 5532(d)(2)
(m) Title 31, United States Code, Section 1342
(n) 45 Comptroller General Opinions 649

DEFINITIONS

1. Clinical Investigation. An organized inquiry into clinical health problems for all conditions that are of concern in providing health care to the beneficiaries of the military health care system including active duty personnel, dependents, and retired personnel.

2. DoD Health Care Personnel. Military personnel, civilian employees, or contract personnel, including military and civilian staff members, assigned to, employed by, or appointed to the USUHS, who provide patient care or patient care support services in military MTFs, DTFs, and/or the USUHS.

3. Donor. An individual, organization, or corporation that gives funds, services, or tangible or intangible property to the Government without any compensation or promise of compensation.

4. Gifts. Any donation of funds, services, or tangible or intangible property from a non-DoD source for which there is no compensation or promise of compensation on behalf of the donor.

5. Grant. An award of funds, services, or tangible or intangible property from a nonprofit organization in support of the CIP that is pursuant to a written agreement.

6. Grantor. Any corporation, foundation, trust, or institution that is operated for the purpose of higher learning or research, is not organized for profit, and does not provide any net earnings to shareholders or individuals.

7. Principal Investigator. A uniformed or civilian individual who is assigned or employed in an MTF, DTF, USUHS, or other DoD research facility, and is responsible for the innovation, experimental design, generation and analysis of data, presentation of reports, and protection of human subjects in the performance of a clinical investigation study.

SUPPLEMENTARY

INFORMATION

DEPARTMENT OF DEFENSE
DIRECTIVES SYSTEM TRANSMITTAL

NUMBER	DATE	DISTRIBUTION
See Below Pen Changes	November 16, 1994	6000 series

ATTACHMENTS

None

ERRATA ADA 272429

INSTRUCTIONS FOR RECIPIENTS

Pen changes to the following DoD Issuances are authorized:

DoD Issuance Number and Date	Change Number
DoD Directive 6000.2, April 8, 1988 Section H. Heading. Delete "AND IMPLEMENTATION" Lines 1 and 2. Delete "Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."	Change 1
DoD Directive 6000.6, August 24, 1977 Section E. Heading. Delete "AND IMPLEMENTATION" Paragraph 2. Delete in its entirety.	Change 1
DoD Directive 6000.8, December 6, 1985 Section G. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 3. Delete "Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) (ASD(HA)) within 120 days."	Change 1
DoD Directive 6010.7, August 27, 1975 Section VIII. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 4. Delete "Three copies of proposed implementing regulations shall be forwarded to the Assistant Secretary of Defense (Health Affairs) within 30 days."	Change 5

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, THIS TRANSMITTAL SHOULD BE FILED WITH THE BASIC DOCUMENT

NUMBER	DATE	DEPARTMENT OF DEFENSE
See Below Pen Changes	November 16, 1994	DIRECTIVES SYSTEM TRANSMITTAL

INSTRUCTIONS FOR RECIPIENTS (continued)

DoD Issuance Number and Date	Change Number
DoD Directive 6010.13, February 3, 1986 Section G. Heading. Delete "AND IMPLEMENTATION" Lines 1 and 2. Delete "Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."	Change 1
DoD Instruction 6010.15, March 10, 1993 Section H. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 3. Delete "Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."	Change 1
DoD Directive 6010.16, March 8, 1988 Section H. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 6. Delete "The Office of the Armed Forces Medical Examiner shall be established within 120 days of the implementation of this Directive, at which time the procedures for the notification of death shall be in effect. The Director of AFIP shall prepare a tri-Service implementing regulation and shall forward one copy of implementing document to the Assistant Secretary of Defense (Health Affairs) within 6 months."	Change 1
DoD Directive 6015.1, December 12, 1988 Section E. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 3. Delete "Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 90 days."	Change 1
DoD Directive 6015.16, April 15, 1986 Section F. Heading. Delete "AND IMPLEMENTATION" Lines 1 and 2. Delete "Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 60 days."	Change 1
DoD Instruction 6025.15, November 9, 1992 Section H. Heading. Delete "AND IMPLEMENTATION" Lines 1 through 3. Delete "The Military Departments shall forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."	Change 1

NUMBER	DATE	DEPARTMENT OF DEFENSE
See Below Pen Changes	November 16, 1994	DIRECTIVES SYSTEM TRANSMITTAL

INSTRUCTIONS FOR RECIPIENTS (continued)

DoD Issuance Number and Date	Change Number
DoD Directive 6420.1, December 9, 1982	Change 2

Section F

Heading. Delete "AND IMPLEMENTATION"

Lines 1 through 3. Delete "Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."

DoD Directive 6430.2, June 21, 1984	Change 1

Section F.

Heading. Delete "AND IMPLEMENTATION"

Lines 1 through 3. Delete "Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days."

EFFECTIVE DATE

The above pen changes are effective immediately. Although the pen changes remove the requirement for DoD Components to issue implementing documents, the DoD issuances are directly applicable to all elements with the Components and the Heads of the DoD Components are responsible for carrying out the DoD guidance.

James L. Elmer

JAMES L. ELMER
Director
Correspondence and Directives